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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,425	07/21/2003	Jeffrey Weitz	GLYCO-0012-C02	4953

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
KHARE, DEVESH	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,425	WEITZ ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-49 is/are pending in the application.

4a) Of the above claim(s) 1-8 and 42-49 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 9-41 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/21/2003.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 9/20/2005.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.4999, applicant is required, to elect a single invention to which the claims must be restricted.

I. Claims 1-8 and 42-45 drawn to a modified low molecular weight heparin (MLMWH) having a molecular weight between 5000-9000 Daltons and the composition thereof.

II. Claims 9-41 and 46-48 drawn to a method for treating thrombotic condition in a mammal with the MLMWH of Group I.

III. Claim 49 drawn to a process for preparing a purified preparation of the MLMWH of Group I.

The inventions listed, as Groups **I-III** do not relate to a single general inventive concept under PCT rule 13.1-13.3. PCT 13.1 states that the international application shall relate to one invention only or to group of inventions linked as to form "a single general inventive concept". PCT 13.2 indicates that such unity of invention is fulfilled only when there is a "technical relationship" among those inventions involving one or more of the same or corresponding "special technical feature".

In the instant Groups **I-III**, a technical relationship" corresponding to the special technical feature is lacking because the special feature for patentability of Groups **I-III** are:

The special technical feature of Group I is considered to be a modified low molecular weight heparin (MLMWH) having a molecular weight between 5000-9000 Daltons and the composition thereof.

The special technical feature of Group II is considered to be a method for treating thrombotic condition in a mammal with the MLMWH of Group I.

The special technical feature of Group III is considered to be a process for preparing a purified preparation of the MLMWH of Group I.

Since the method for treating thrombotic condition in a mammal with the MLMWH of Group I is different from that of a modified low molecular weight heparin (MLMWH) having a molecular weight between 5000-9000 Daltons and the composition thereof and a process for preparing a purified preparation of the MLMWH and involve different procedural steps they are not so uniquely linked to each other. It is noted that art, which may render obvious or anticipate one of the groups would not necessarily anticipate the other group. See Baron et al. (U.S. Patent 5,707,973): Baron et al. disclose the preparation of a low molecular weight heparin, modified by fractionation (abstract).

Because the groups are patentably distinct, the search for one group is not coextensive with the others and each must be searched independently and therefore would entail a burdensome search.

Accordingly, unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper.

A telephone call was made to Tony Zelano on 09/06/05 to request an oral election to the above restriction requirement. During telephone conversation with Tony Zelano on 09/20/05, a provisional election was made without traverse to prosecute the invention of Group II, claims 9-41 and 46-48. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-8, 42-45 and 49 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 9-41 and 46-48 are currently pending in this application.

An action on the merits of claims 9-41 and 46-48 is contained herein below.

Objection

Claims 46-48 are objected to since they are dependent on the non-elected claim 43.

Claims 46-48 are not been further treated on the merits.

Appropriate correction is required.

35 U.S.C. 112, second paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **9-41** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"Modified" is a relative term that renders the claims indefinite in all occurrences. In the absence of the specific modifications to the claimed compound core or distinct language

to describe the structural modifications or the chemical names of modified or substituted compounds claimed, the identity of said modified compounds would be difficult to describe and the metes and bounds of said modified compounds applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

Claims which depend from an indefinite claim which fail to obviate the indefiniteness of the claim from which they depend are also seen to be indefinite and are also rejected for the reasons of record.

35 U.S.C. 112, first paragraph rejection

***Claims* 22-38** are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention of record. The specification, while being enabling for the use of a modified MLMWH having molecular weight between 5,000-9,000 Daltons in a method for treating a thrombotic condition in a mammal does not reasonably provide enablement for preventing the formation of a thrombus in a mammal at risk of developing thrombosis with MLMWH having molecular weight between 5,000-9,000 Daltons. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

The factors regarding undue experimentation have been summarized in *In re Wands,* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);

(2) The amount of direction or guidance presented;

(3) The presence or absence of working examples of the invention;

(4) The nature of the invention;

(5) The state of the prior art;

(6) The predictability or unpredictability of the art;

(7) The breadth of the claims; and

(8) The relative skill of those in the art.

1. QUANTITY OF EXPERIMENTATION

With regard to factor one the quantity of experimentation needed, for preventing the formation of a thrombus in a mammal at risk of developing thrombosis with MLMWH having molecular weight between 5,000-9,000 Daltons, applicant intends to utilize a method of prevention, would require undue experimentation. At the very least, experimentation correlative to establishing the broad spectrum of efficacy should be

provided. The absence of specific disclosures or the correlation of data to support applicant's assertions, invites the skilled artisan to engage in undue experimentation.

2. GUIDANCE PROVIDED

There is little guidance given in the specification as to the specific use of an effective amount of modified MLMWH having molecular weight between 5,000-9,000 Daltons to a mammal for preventing the formation of a thrombus in a mammal at risk of developing thrombosis. This lack of guidance would indeed impose the burden of undue experimentation in determining the degree, if any, for the prevention of mammal health conditions set forth. There is not seen any guidance in the specification drawn to establishing a correlation between the use of an effective amount of modified MLMWH having molecular weight between 5,000-9,000 Daltons to a mammal and preventing the formation of a thrombus in a mammal at risk of developing thrombosis.

3. WORKING EXAMPLES IN SPECIFICATION

The examples A-D disclose the preparation of MLMWH; clinical results; and comparison of MLMWH with other known ant-coagulants. The EXAMPLES advanced in the instant specification are not seen as sufficient to support the breadth of the claims for use of an effective amount of modified MLMWH having molecular weight between 5,000-9,000 Daltons to a mammal for preventing the formation of a thrombus in a mammal at risk of developing thrombosis.

4. NATURE OF THE INVENTION

It is known in this art that certain MLMWH are useful in prophylaxis and treatment of thrombotic conditions including venous and arterial thrombosis (see Baron et al.). The exact mechanism of action and the effects of these MLMWH may be found in the Baron et al. (Col.4, line 58 thru col.5, line 4 and claims 7-12).

5. STATE OF THE PRIOR ART

The instant claimed method is drawn to the use of an effective amount of modified MLMWH having molecular weight between 5,000-9,000 Daltons to a mammal for preventing the formation of a thrombus in a mammal at risk of developing thrombosis.

The following references are cited to show the state of the prior art:

Baron et al. (U.S. Patent 5,707,973)- disclose that MLMWH are useful in prophylaxis and treatment of thrombotic conditions including venous and arterial thrombosis (see Baron et al.).

Wong et al. (U.S. Patent 6,346,517)- disclose a combination therapy for the treatment of thromboembolic disorders using a low molecular weight heparin.

6. THE PREDICTABILITY OF THE ART

To extrapolate the data from the class of compounds represented by modified MLMWH, for preventing the formation of a thrombus in a mammal at risk of developing thrombosis is not seen to be disclosed in the prior art. Neither the specification nor the prior art provides adequate guidance for equivocating the modified MLMWH, in method for preventing the formation of a thrombus in a mammal at risk of developing thrombosis.

The extrapolation is not seen to be based upon data, which would adequately substantiate the prevention of mammal health conditions instantly claimed.

7. BREATH OF THE CLAIMS

Claims 1-8 and 42-45 are drawn to a modified low molecular weight heparin (MLMWH) having a molecular weight between 5000-9000 Daltons and the composition thereof. Claims 9-41 and 46-48 drawn to a method for treating or preventing thrombotic condition in a mammal with the MLMWH of Group I. Claim 49 drawn to a process for preparing a purified preparation of the MLMWH of Group I.

8. THE RELATIVE SKILL IN THE ART

Further, there is no enabling description of the administration of a pharmacologically acceptable dose of a modified low molecular weight heparin (MLMWH) compound to a mammal, for preventing the formation of a thrombus in a mammal at risk of developing thrombosis. The worker of ordinary skill in the art would not be able to practice the instantly claimed method given the limited guidance provided by the disclosure herein. The mere statements that the compounds of the instant invention are likely to be effective, or expected to be effective on the basis of limited *in vitro* test data, are insufficient to enable the worker of ordinary skill in the art to practice the invention commensurate in scope with these claims. It is well known and established that the "law requires that disclosure in an application shall inform those skilled in the art how to use appellant's alleged discovery, not how to find out how to use it for themselves." *In re Gardner et al.,* 166 USPQ 138(CCPA 1970).

Provisional "Non-Statutory" Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-38 of U.S. Patent No.6, 075,013 ('013). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in each of the application and the '013 patent are directed to substantially same subject matter, i.e., in the instant claims the invention is claimed in terms of the specific use of an effective amount of modified MLMWH having molecular weight between 5,000-9,000 Daltons to a mammal for treating or preventing the formation of a thrombus in a mammal at risk of developing thrombosis, while in the '013 patent it is claimed in terms of a method for treating or preventing a thrombotic condition or the formation of a thrombus in a mammal by administering to said mammal

a modified MLMWH having an anti-factor IIa activity of about 40 U/mg to about 100 U/mg, and an anti-factor Xa activity of about 90 U/mg to about 150 U/mg. The modified MLMWH having an anti-factor IIa activity of about 40 U/mg to about 100 U/mg, and an anti-factor Xa activity of about 90 U/mg to about 150 U/mg may well be varied in terms of its inherent activity, in this case to accomplish a method for treating or preventing the formation of a thrombus in a mammal at risk of developing thrombosis.

Therefore the claims are co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is 571-272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 571-272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
October 13,2005